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| REC'D 25 NOV 2002 | |
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|--|--|--|
| Applicant's or agent's file reference 90337.147601 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US01/46882 | International filing date (day/month/year) 08 NOVEMBER 2001 | Priority date (day/month/year) 08 NOVEMBER 2000 |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 31/74 and US Cl.: 424/78.04 | | |
| Applicant BIO-CONCEPT LABORATORIES | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

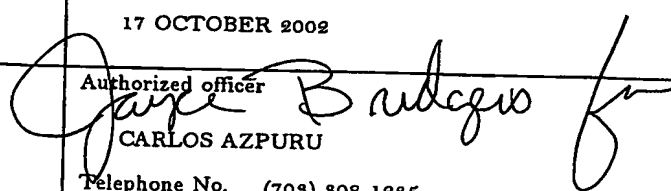
2. This REPORT consists of a total of 4 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 06 JUNE 2002 | Date of completion of this report 17 OCTOBER 2002 |
| Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box POT Washington, D.C. 20231 | Authorized officer  CARLOS AZPURU |
| Facsimile No. (703) 305-3230 | Telephone No. (703) 308-1235 |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/46882

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☒ the description:

pages 1-15

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of

☒ the claims:

pages 16 and 17

pages NONE

pages NONE

pages NONE

, as originally filed
, as amended (together with any statement) under Article 19
, filed with the demand
, filed with the letter of

☒ the drawings:

pages NONE

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of

☒ the sequence listing part of the description:

pages NONE

pages NONE

pages NONE

, as originally filed
, filed with the demand
, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig. NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US01/46882

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

| | | | |
|-------------------------------|--------|--------------|-----|
| Novelty (N) | Claims | <u>2</u> | YES |
| | Claims | <u>1,3-7</u> | NO |
| Inventive Step (IS) | Claims | <u>None</u> | YES |
| | Claims | <u>1-7</u> | NO |
| Industrial Applicability (IA) | Claims | <u>1-7</u> | YES |
| | Claims | <u>None</u> | NO |

2. citations and explanations (Rule 70.7)

Claim 2 lacks novelty under PCT article 33(2) as being anticipated by ASGHARIAN et al.

ASGHARIAN et al disclose an ophthalmic solution comprising 0.01 to 0.0001 percent by weight of a peroxide agent and 0.1 to 500 parts per million of a cationic, polymeric preservative. A buffer, surfactant, and vial are also disclosed (see column 8, lines 20-44). The claims are anticipated by ASGHARIAN et al.

Claim 2 meets the criteria set out in PCT Article 33(2) for anticipation.

Claims 1-7 lack an inventive step under PCT Article 33(3) as being obvious over ASGHARIAN et al in view of STOCKEL.

ASGHARIAN et al disclose an ophthalmic solution comprising 0.01 to 0.0001 percent by weight of a peroxide agent and 0.1 to 500 parts per million of a cationic, polymeric preservative. A buffer, surfactant, and vial are also disclosed (see column 8, lines 20-44). ASGHARIAN et al differs in that the specific preservative of claim 2 is not disclosed.

STOCKEL discloses another ophthalmic formulation containing the polyoxyalkylenediamine biquanide of claim 2. Therefore, those of ordinary skill would have found it well within their skill to use the preservative of STOCKEL for its art recognized therapeutic properties in the ophthalmic formulation disclosed by ASGHARIAN et al. Those of ordinary skill would further expect similar therapeutic results from the composition of ASGHARIAN et al, in view of the specific preservative of STOCKEL. Therefore, the instant invention would have been obvious given the ophthalmic composition of ASGHARIAN et al, in view of the specific preservative of STOCKEL.

Claims 1-7 meet the criteria for industrial applicability under PCT Article 33(4) since the composition can be used for various ophthalmic treatments.

(Continued on Supplemental Sheet.)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

V. 2. REASONED STATEMENTS - CITATIONS AND EXPLANATIONS (Continued):

----- NEW CITATIONS -----

NONE